



Office of Nutritional Products
Labelling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
20th September 2005

0939 5 OCT 28 P2:12

OCT 17

Dear Sir or Madam,

This letter serves as a 30 day notification pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 (DSHEA), that Boots Retail USA is using the following statements on the label or in the labelling of

Boots Detox 5 Day Introductory Kit Total Body Cleanse

"The core product in this kit, the 5-Day Plan is a pleasant tasting supplement made from a blend of ingredients that target your detoxifying organs and, in conjunction with a set of simple nutritional guidelines, encourage your body's waste disposal organs to flush out impurities and help protect from the dangers of free radicals."

"The 5 Day Introductory Kit for detoxification helps you to feel purified, revitalised and re-energised in just five days."

"The kit contains a selection of products chosen to help stimulate your system's natural processes and leave you feeling thoroughly detoxified."

The kit contains the following dietary supplement products and associated statements:-

1. Boots Detox 5 Day Plan Strawberry Flavour Dietary Supplement Total Body Cleanse,

consisting of;

Vials (x 5)

(dietary ingredients: Grape vine leaf extra (Vitis vinifera) 700mg and Pine bark extract (Pycnogenol) 30mg)

"Help combat the effects with this 5 day plan that helps re-energise your detoxifying organs to leave you feeling revitalised."

"Made from a blend of ingredients that target your detoxifying organs, the plan helps to flush away impurities from your body. The plan contains ingredients that battle against toxic substances and help protect from the dangers of free radicals."

"If your body needs a rest from the stresses of a modern hectic lifestyle then this 5 day plan will help combat over indulgence to remove impurities and re-energise".

975 0162

LET

16788

- 7018



The kit also contains the following Cosmetic style products:

Body Brush

Face Mask

Salt Scrub

These statements are accompanied by the required disclaimer. To the best of my knowledge, the information contained in this notice is complete and accurate and the company has substantiation that these statements are truthful and not misleading.

Sincerely,

A handwritten signature in cursive script, appearing to read "A. Pattie".

Adèle Pattie
International Regulatory Affairs

Boots Retail USA Inc.,
Stamford,
CT 06901



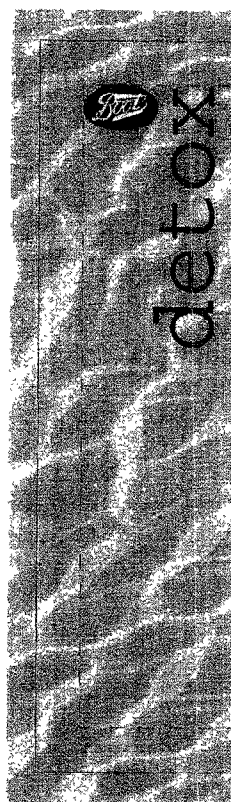
Boots
detox

5 Day Introductory Kit
TOTAL BODY CLEANSE

Your body is designed to naturally flush out impurities. But a busy modern lifestyle can leave your system struggling to cope, leaving you feeling tired and sluggish. The 5 Day Introductory Kit for detoxification helps you to feel purified, revitalised and re-energised in just five days.*

The kit contains a selection of products chosen to help stimulate your system's natural processes and leave you feeling thoroughly detoxified.* With treatments to target digestion, circulation and the skin, the 5 Day Introductory Kit gently yet effectively neutralises the effects of over indulgence for a cleaner, brighter new you!

[illegible]



Face Mask

WARMING CLEANSER

Help your skin recover from the stresses of daily life with this self-heating, deep cleansing facial treatment for fresher skin.

10 ml e 0.33 US FL. Oz.

Detox Face Mask

The Boots Detox product range works in harmony with your body to help flush away impurities and stimulate your body's natural detoxifying systems, leaving you purified and revitalised.

This intensive, purifying face mask gently opens the pores to help draw out impurities and absorb excess oils, leaving the skin thoroughly cleansed. The mask contains anti-oxidant ingredients to help protect against free radicals.

To Use: Wet face then pat dry until damp. Using the whole sachet, massage the contents in your hand then apply the mask to your face. Leave for at least 2-3 minutes before rinsing.

Warning: Avoid the eye area. If you do get product in your eyes wash them immediately with plenty of water and seek medical attention.

Ingredients: Butylene glycol, Zeolite, PEG-8, Kaolin, Dimethicone, Lauryl methacrylate/glycol dimethacrylate cross polymer, Methyl gluceth-20, Hydroxypropylcellulose, Parfum (Fragrance), Ascorbyl palmitate, Vitis vinifera (Grape) seed oil, CI 77501 (Titanium dioxide).

Mfd in the UK for BB Ltd NG2 3AA UK
Dist in USA by Boots Retail USA Inc Stamford CT 06901
USA: Questions? 1-866-75-BOOTS

www.boots.com
47-29-609 LEBW8



Face Mask

WARMING CLEANSER

Help your skin recover from the stresses of daily life with this self-heating, deep cleansing facial treatment for fresher skin.

10 ml e 0.33 US FL. Oz.

Detox Face Mask

The Boots Detox product range works in harmony with your body to help flush away impurities and stimulate your body's natural detoxifying systems, leaving you purified and revitalised.

This intensive, purifying face mask gently opens the pores to help draw out impurities and absorb excess oils, leaving the skin thoroughly cleansed. The mask contains anti-oxidant ingredients to help protect against free radicals.

To Use: Wet face then pat dry until damp. Using the whole sachet, massage the contents in your hand then apply the mask to your face. Leave for at least 2-3 minutes before rinsing.

Warning: Avoid the eye area. If you do get product in your eyes wash them immediately with plenty of water and seek medical attention.

Ingredients: Butylene glycol, Zeolite, PEG-8, Kaolin, Dimethicone, Lauryl methacrylate/glycol dimethacrylate cross polymer, Methyl gluceth-20, Hydroxypropylcellulose, Parfum (Fragrance), Ascorbyl palmitate, Vitis vinifera (Grape) seed oil, CI 77891 (Titanium dioxide).

Mfd in the UK for BB Ltd NG2 3AA UK
Dist in USA by Boots Retail USA Inc Stamford CT 06901
USA: Questions? 1-866-75-BOOTS

www.boots.com
47-29-609 LEBW8



COUNTRY AREA:	VALENTINE	ARTWORK CODE:	H1844	COMPONENT CODE:	LEBW8		Globalisation
FILENAME:	H1844/VAL/XLAZO/DetoxFaceMskSch1			DATE:	4/5/04		
COLOURS USED:				ARTWORKER:	Alison/DF/DT/LW/DT		
CLEAR				CHARGE CODE:	30008/1469	SPEC:	80 x 100mm
SUBSTRATE COLOUR				PRINT PROCESS:	Flexo		
PACKAGING TECHNOLOGISTS APPROVAL:	Signed: _____ Date: _____			PACK TECH:	David Fowler/Healthcare		
ARTWORK NOTES:	?			PLACED IMAGES:	? (If applicable)		
				IF APPLICABLE: PLEASE NOTE THAT THE BARCODE HAS BEEN CREATED WITH 0 BAR WIDTH REDUCTION. IF YOU DESIRE OTHER IMAGE NEW ART			



THE BOOTS COMPANY
STRATEGIC MARKETING
DIV
Mac Artwork Studio,
Strategic Marketing Unit,
The Boots Company,
D96 Building, Beeston,
Nottingham, NG2 3AA.
Tel: 0115 959 1859/3479
or 0115 968 6340
/6241/6137.
Fax: 0115 959 4427.
ISDN: 0115 840 4044.
e-mail:
name@bonartwork.demon.co.uk



detox

Your pocket guide

The hows and whys, the benefits and the results.

An easier, more natural way to look and feel better.



This booklet contains comprehensive help and advice on the detox process. Everything from the nutritional and lifestyle changes you can make, through to why the simplest of things – like laughing more – can help. Hopefully its contents will answer many of your questions and at the same time give you advice on how to make detoxing a treat rather than a chore.

www.boots.com

08/01 002088 PJTT5

RANGE **detox** PAGE NO **16 & 1**



CUSTOMER & CONTACT		DESCRIPTION				COLOURS		 	
BCM		Detox Leaflet Amends						PROG	
CUSTOMER ORDER No.	ACCOUNT EXECUTIVE	OPERATOR				<div>Cyan</div>	<div>Magenta</div>	Q.C.D.	
To Follow	A. Campbell	Gareth Prate				Yellow	Black	1	
TRINITY WORKS No.	DATE	PROOF	LABEL SIZE	SCREEN	Total No. of Colours 4				
68244	1/6/04	No.2	77 x 77	150#					

Approved
Ian Beadle
09 SEP 04

Detox. How, why, what?

Pollutants, exhaust fumes, alcohol, smoke and pesticides are all everyday parts of 21st century life, and are all capable of contributing to the impurity build-up within our bodies. An increased exposure to these impurities can often leave you feeling less than 100% – lacking in energy and vitality, and can reduce your body's ability to digest food and eliminate waste. Detoxing is an excellent way to give your body a spring clean – reducing the level of excess waste and impurities built-up by everyday living. By watching what you eat and drink and with a few simple lifestyle changes, you should soon start to see and feel the benefits in both your body and mind.



RANGE **detox** PAGE NO **2 & 3**



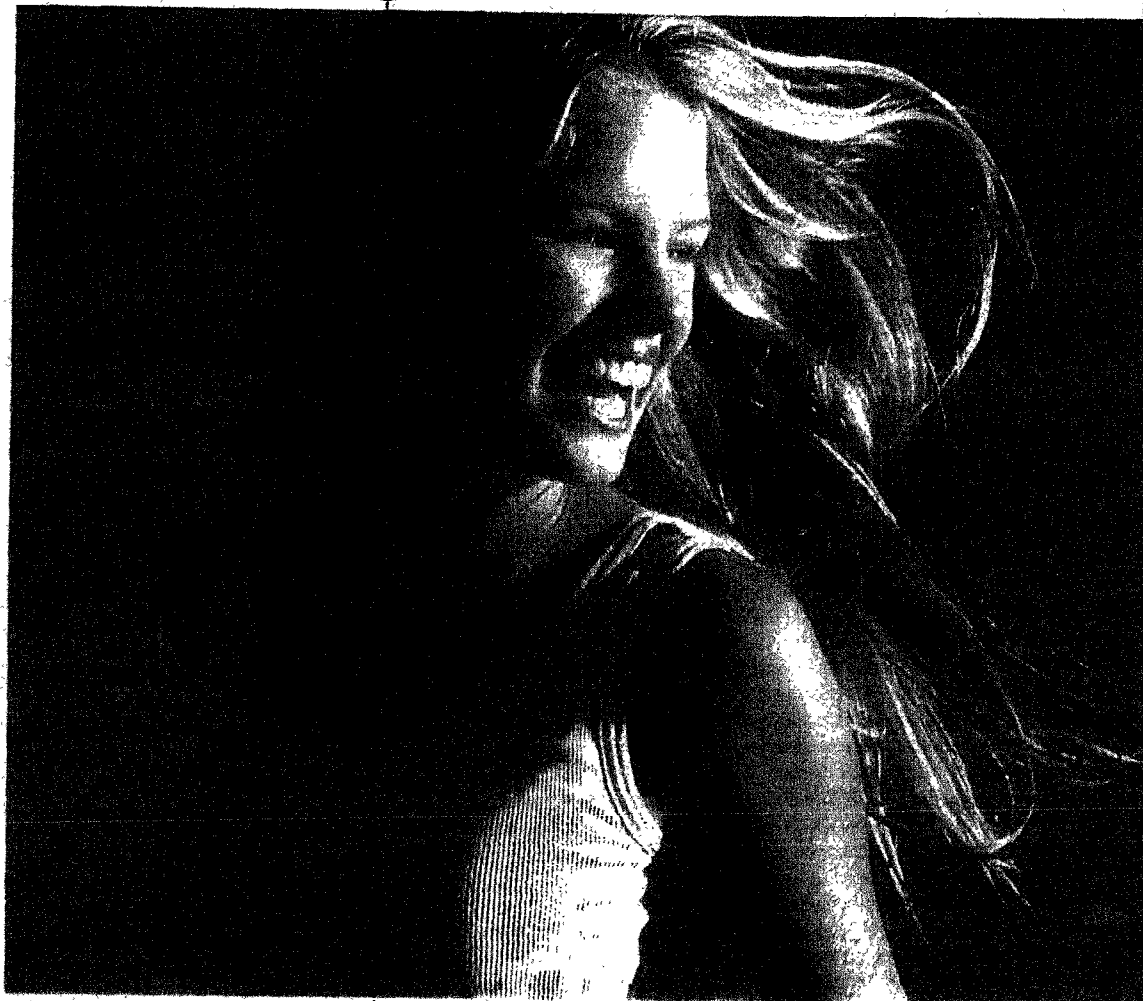
CUSTOMER & CONTACT		DESCRIPTION					COLOURS		PROG		Q.C.I.D.	
BCM		Detox Leaflet Amends							1			
CUSTOMER ORDER No.	ACCOUNT EXECUTIVE	OPERATOR					Cyan Magenta					
To Follow	A. Campbell	Gareth Prate					Yellow Black					
TRINITY WORKS No.	DATE	PROOF	LABEL SIZE	SCREEN								
68244	1/6/04	No.2	77 x 77	150#				Total No. of Colours 4				

Approved
Ian Beadle
19 SEP 04

The benefits of detoxing

Differences between individuals, in terms of metabolism and the patterns of previous lifestyle, will affect the degree to which you will be able to feel the benefits of detoxing, but there is little doubt that you will experience some beneficial changes.

As the impurity build-up is flushed away you will feel re-energised and revitalised as your body's systems are optimised. As your internal impurity levels reduce this can lead to clearer skin, healthier looking hair and increased energy levels. Detoxing is part of a healthier approach to life, rather than a diet programme. However the change in lifestyle may mean that weight loss is a side effect. What's more, abstaining from some of your usual bad habits can be the first steps to cutting down or giving up.



RANGE **detox** PAGE NO **4 & 5**



CUSTOMER & CONTACT		DESCRIPTION			COLOURS	
BCM		Detox Leaflet Amends			Cyan Magenta	
CUSTOMER ORDER No.		ACCOUNT EXECUTIVE		OPERATOR	Yellow Black	
To Follow		A. Campbell		Gareth Prate		
TRINITY WORKS No.		DATE	PROOF	LABEL SIZE	SCREEN	
68244		1/6/04	No.2	77 x 77	150#	
Total No. of Colours 4						



Approved
Ian Beadle
20 SEP 04

How detoxing works

Detoxing is a way of removing excess waste and impurities from your body. The impurities we pick up in our everyday lives are carried around the body in our blood. They are carried to the liver, where they are filtered and converted into compounds that other organs are able to process and expel. When detoxing you should include elements for all the major organs involved in processing impurities. The Boots Detox range works in harmony with your body, helping the organs flush away impurities.

From plans for your whole body to products that target specific detoxifying organs, such as the skin, and the digestive system, our range can help both improve and supplement the cleansing process. Whilst our products will help to detoxify your body, the lifestyle changes described in this booklet will ensure that you get the most benefit from the time that you are investing. What's more, our products are designed to not only be effective, but also pleasant, and in some cases are decadently pampering, while still contributing to your detox. Sticking to the healthy lifestyle may not seem so bad when you can treat yourself to our gently warming face mask.

Our range contains plans and kits that will help you carry out a head to toe detox. They contain ingredients that target all the major detoxifying organs to give a general overhaul of your purifying processes.

RANGE **detox** PAGE NO **6 & 7**



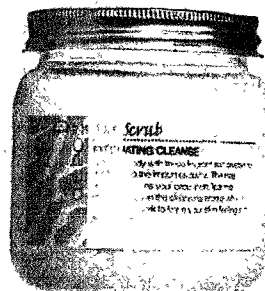
CUSTOMER & CONTACT		DESCRIPTION				COLOURS			
BCM		Detox Leaflet Amends				Cyan Magenta			
CUSTOMER ORDER No.	ACCOUNT EXECUTIVE	OPERATOR							
To Follow	A. Campbell	Gareth Prate				Yellow Black			
TRINITY WORKS No.	DATE	PROOF	LABEL SIZE	SCREEN					
68244	1/6/04	No.2	77 x 77	150#	Total No. of Colours 4				

Approved
Ian Seadle
09 SEP 04

Detox your skin and circulation

The major internal organs involved in removing toxins from your body are your lungs, liver, kidneys and digestive system. You breathe out impurities when you exhale, so deeper breathing is beneficial. By optimising your digestive process you will expel impurities more quickly and maximise your ability to absorb nutrients. The range contains specific products to help with this. Your kidneys are also important - drinking lots of water is the best way of helping them.

detox
Digestive
Cleanse



RANGE **detox** PAGE NO **8 & 9**



CUSTOMER & CONTACT		DESCRIPTION				COLOURS				
BCM		Detox Leaflet Amends								
CUSTOMER ORDER No.	ACCOUNT EXECUTIVE	OPERATOR								
To Follow	A. Campbell	Gareth Prate								
TRINITY WORKS No.	DATE	PROOF	LABEL SIZE	SCREEN						
68244	1/6/04	No.2	77 x 77	150#						
		Total No. of Colours 4								

Approved
Ian Beadles

The Essentials While Detoxing

Whilst our Detox range is undoubtedly a great way to aid the detoxifying process, there are many other things you can make part of your daily routine to help maximise the effects.

Drink more fluids

You should aim to drink at least 1.5 litres (3 pints) of fluids a day, preferably water. This will help flush your system and rehydrate your body.

Change your diet

A change to a more balanced, healthier diet can work wonders for your system and can also result in weight loss and increased energy levels. As a general rule, eat and drink natural, fresh produce.



Good detoxifying foods include:

Fruit – fresh or dried, Vegetables – preferably raw or steamed, Nuts, pulses and seeds, Fish, Brown rice, Wholemeal bread, Olive, walnut or sesame oil, Garlic, Herbal teas, Fruit juice – preferably not made from concentrate, Vegetable juice

Things to avoid or moderate



Dairy products (difficult to digest), processed or convenience food, artificially sweetened food, tea, coffee and alcohol (dehydrates your body), candy and chocolate

If possible you should also try to stop smoking and avoid smoky environments.



RANGE **detox** PAGE NO **10 & 11**



CUSTOMER & CONTACT		DESCRIPTION				COLOURS		 
BCM		Detox Leaflet Amends						
CUSTOMER ORDER No.		ACCOUNT EXECUTIVE		OPERATOR		<div>CyanMagenta</div> <div>YellowBlack</div>		
To Follow		A. Campbell		Gareth Prate				
TRINITY WORKS No.		DATE	PROOF	LABEL SIZE	SCREEN			
68244		1/6/04	No.2	?? x ??	150#			
Total No. of Colours 4								

Approved
Ian Beadle

Take the Holistic Approach*Exercise*

One of the best ways of enhancing the detoxifying process is to take some form of regular exercise. Anything from visiting the gym to walking the dog will help improve both your circulation and metabolic rate and get internal organs working.

Deep breathing

Taking deep breaths can help to expel impurities from your lungs. You should try breathing deeply for at least 5 minutes every day.

Improve your environment

Your home or office can be as prone to impurities as the outside. Green plants are an excellent way of removing airborne pollutants, and ionisers, humidifiers and oil burners are all great ways of improving the atmosphere.

Potential side effects

When detoxing you may experience certain minor side effects. These often depend on your lifestyle prior to detoxification. For example, someone who usually drinks a lot of coffee may experience mild headaches as their body adjusts to the change in caffeine levels.

Common side effects

Mild headaches – caused by your body learning to live without chemicals such as alcohol, sugar and caffeine. These usually appear on day 2 or 3 of the detox and can last for up to 24 hours. Drink lots of fluid and make time for relaxation.

Spots – The skin is the body's biggest organ of elimination, so the appearance of spots during a detox is not uncommon. They can appear as early as day 3 and can last throughout the detox process – drinking plenty of water will help.

Increased bowel movements – this is completely normal and is a sure sign that your body is starting to cleanse itself.

A furry tongue – Again a sure sign that the body is removing impurities. Use a mouthwash or try scraping your tongue with a toothbrush.

Lulls in energy during the first few days – Your body will be used to instant energy snacks. It will take a few days to adjust to the more gradual energy release replacements. These side effects should be minor in nature, and only last for a few days.

Why not try detoxing with a friend?
It's a great way to overcome any potential pitfalls and gain the extra resolve that's sometimes needed to stick it out.

RANGE **detox** PAGE NO **12 & 13**



CUSTOMER & CONTACT		DESCRIPTION				COLOURS		PROG	
BCM		Detox Leaflet Amends				Cyan Magenta		1	
CUSTOMER ORDER No.		ACCOUNT EXECUTIVE		OPERATOR		Yellow Black		Q.C.I.D.	
To Follow		A. Campbell		Garoth Prate					
TRINITY WORKS No.		DATE	PROOF	LABEL SIZE	SCREEN				
68244		1/6/04	No.2	77 x 77	150#				
						Total No. of Colours 4			

Approved
Ian Boodle
09 SEP 04